Docket No.: 62138US(49949)

## **AMENDMENTS TO THE CLAIMS**

Please amend claims 2, 3 and 17. The following listing of claims will replace all prior versions, and listings, of the claims in the application.

- 1. (Cancelled)
- 2. (Currently amended) A method for preventing or treating overactive bladder in a patient comprising administering to a patient in need thereof an effective amount of a Vitamin D<sub>3</sub> compound thereby preventing or treating overactive bladder in said patient; wherein the Vitamin D<sub>3</sub> compound is not a compound of formula

$$R_1$$
 $R_2$ 
 $R_4$ 
 $R_3$ 
 $R_4$ 
 $R_3$ 
 $R_4$ 
 $R_3$ 
 $R_4$ 
 $R_4$ 
 $R_3$ 
 $R_4$ 
 $R_4$ 
 $R_4$ 
 $R_5$ 
 $R_4$ 
 $R_5$ 
 $R_4$ 
 $R_5$ 
 $R_4$ 
 $R_5$ 
 $R_4$ 
 $R_7$ 
 $R_8$ 

wherein:

X<sub>1</sub> is H<sub>2</sub> or CH<sub>2</sub>;

A<sub>2</sub> is a single, a double or a triple bond;

 $R_1$ ,  $R_2$ ,  $R_3$  and  $R_4$  are each independently  $C_1\text{-}C_4$  alkyl, hydroxyalkyl, or fluoroalkyl;

Z is -OH, -NH2 or -SH;

the configuration at  $C_{20}$  is R or S; or pharmaceutically acceptable esters[,] <u>and salts[,]</u> and prodrugs thereof; and

wherein the Vitamin D<sub>3</sub> compound is not a compound of formula

$$R_3$$
 $R_4$ 
 $R_5$ 
 $R_6$ 
 $R_6$ 
 $R_6$ 

Docket No.: 62138US(49949)

## wherein:

 $X_1$  and  $X_2$  are each independently  $H_2$  or  $CH_2$ , provided  $X_1$  and  $X_2$  are not both = $CH_2$ ;  $R_1$  and  $R_2$  are each independently hydroxyl,  $OC(O)C_1$ - $C_4$  alkyl, OC(O)hydroxyalkyl or OC(O)haloalkyl, provided that  $R_1$  and  $R_2$  are not both hydroxyl;  $R_3$  and  $R_4$  are each independently hydrogen,  $C_1$ - $C_4$  alkyl, hydroxyalkyl or haloalkyl or  $R_3$  and  $R_4$  taken together with  $C_{20}$  form  $C_3$ - $C_6$  cycloalkyl; and  $R_5$  and  $R_6$  are each independently  $C_1$ - $C_4$  alkyl, hydroxyalkyl or haloalkyl; or pharmaceutically acceptable esters[,] and salts[,] and prodrugs thereof.

- 3. (Currently amended) The method according to claim 2, which further comprises the step of obtaining or synthesizing the Vitamin D<sub>3</sub> compound.
- 4. (Previously presented) The method according to claim 3, wherein the Vitamin D<sub>3</sub> compound is formulated in a pharmaceutical composition together with a pharmaceutically acceptable diluent or carrier.
- 5. (Cancelled)
- 6. (Cancelled)

Dated September 10, 2008

7. (Withdrawn) A kit containing a Vitamin D compound together with instructions directing administration of the Vitamin D compound to a patient in need of prevention or treatment of bladder dysfunction thereby to prevent or treat bladder dysfunction in

said patient.

8. (Withdrawn) A kit according to claim 7 wherein the Vitamin D compound is formulated in a pharmaceutical composition together with a pharmaceutically acceptable diluent or carrier.

9. (Previously presented) The method according to claim 2, wherein said Vitamin

D<sub>3</sub> compound is a Vitamin D receptor agonist.

10 - 12. (Cancelled)

13. (Previously presented) The method according to claim 2, wherein said patient is

a male.

14. (Cancelled)

15. (Previously presented) The method according to claim 2, wherein said patient is

a female.

16. (Previously Presented) The method according to claim 2, wherein the patient is

a human.

17. (Currently Amended) The A method according to claim 2, wherein said Vitamin

D<sub>3</sub>-compound isfor preventing or treating overactive bladder in a patient comprising

administering to a patient in need thereof an effective amount of a compound of the

formula

Docket No.: 62138US(49949)

wherein:

X is H<sub>2</sub> or CH<sub>2</sub>;

R<sub>1</sub> is hydrogen, hydroxy or fluorine;

R<sub>2</sub> is hydrogen or methyl;

 $R_3$  is hydrogen or methyl, wherein when  $R_2$  or  $R_3$  is methyl,  $R_3$  or  $R_2$  must be hydrogen;

R<sub>4</sub> is methyl, ethyl or trifluoromethyl;

R<sub>5</sub> is methyl, ethyl or trifluoromethyl;

A is a single or double bond; and

B is a single, E-double, Z-double or triple bond; or pharmaceutically acceptable esters and salts thereof.

- 18. (Previously Presented) The method according to claim 17, wherein each of  $R_4$  and  $R_5$  is methyl or ethyl.
- 19. (Previously presented) The method according to claim 18, wherein said Vitamin D<sub>3</sub> compound is 1-alpha-fluoro-25-hydroxy-16,23E-diene-26,27-bishomo-20-epi-cholecalciferol, having the formula:

Application No. 10/573,164 Amendment and Response to Final Office Action

Dated September 10, 2008

Docket No.: 62138US(49949)

- 20. (Previously presented) The method according to claim 2, wherein said Vitamin D<sub>3</sub> compound is 1,25-dihydroxy-16-ene-23-yne cholecalciferol.
- 21. (Previously presented) The method according to claim 2, wherein said Vitamin  $D_3$  compound is 1,3-di-O-acetyl-1,25-dihydroxy-16,23Z-diene-26,27-hexafluoro-19-nor-cholecalciferol, having the formula:

- 22. (Previously presented) The method according to claim 2, wherein said Vitamin  $D_3$  compound is calcitriol.
- 23. (Previously presented) The method according to claim 2, wherein said Vitamin  $D_3$  compound is a compound of the formula

$$R_{1}$$
 $R_{2}$ 
 $R_{3}$ 
 $R_{4}$ 
 $R_{3}$ 
 $R_{4}$ 
 $R_{3}$ 
 $R_{4}$ 
 $R_{3}$ 

wherein:

 $X_1$  and  $X_2$  are  $H_2$  or  $CH_2$ , wherein  $X_1$  and  $X_2$  are not  $CH_2$  at the same time;

A is a single or double bond;

A<sub>2</sub> is a single, double or triple bond;

 $A_3$  is a single or double bond;

 $R_1$  and  $R_2$  are hydrogen,  $C_1$ - $C_4$  alkyl or 4-hydroxy-4-methylpentyl, wherein  $R_1$  and  $R_2$  are not both hydrogen;

 $R_5$  is hydrogen,  $H_2$  or oxygen;

 $R_3$  is  $C_1\text{-}C_4$  alkyl, hydroxyalkyl or haloalkyl; and

R<sub>4</sub> is C<sub>1</sub>-C<sub>4</sub> alkyl, hydroxyalkyl or haloalkyl.

- 24. (Previously presented) The method according to claim 23, wherein the compound is 1,25-dihydroxy-16-ene-23-yne cholecalciferol.
- 25. (Previously presented) The method according to claim 2, wherein said Vitamin  $D_3$  compound is a compound of the formula

$$R_3$$
 $R_4$ 
 $R_5$ 
 $R_6$ 
 $R_7$ 
 $R_7$ 
 $R_1$ 

A<sub>1</sub> is single or double bond;

Dated September 10, 2008

A<sub>2</sub> is a single, double or triple bond;

 $X_1$  and  $X_2$  are each independently  $H_2$  or  $CH_2$ , provided  $X_1$  and  $X_2$  are not both  $CH_2$ ;  $R_1$  and  $R_2$  are each independently  $OC(O)C_1$ - $C_4$  alkyl, OC(O)hydroxyalkyl or OC(O)haloalkyl;

 $R_3$ ,  $R_4$  and  $R_5$  are each independently hydrogen,  $C_1$ - $C_4$  alkyl, hydroxyalkyl, or haloalkyl, or  $R_3$  and  $R_4$  taken together with  $C_{20}$  form  $C_3$ - $C_6$  cycloalkyl;  $R_6$  and  $R_7$  are each independently  $C_{1-4}$ alkyl or haloalkyl; and  $R_8$  is H, -COC<sub>1</sub>- $C_4$ alkyl, -COhydroxyalkyl or -COhaloalkyl.

26. (Previously presented) The method according to claim 25, wherein the compound is 1,3-di-O-acetyl-1,25-dihydroxy-16,23Z-diene-26,27-hexafluoro-l9-nor-cholecalciferol:

Dated September 10, 2008

27. (Previously presented) The method according to claim 2, wherein said Vitamin  $D_3$  compound is a compound of the formula:

 $X_1$  is  $H_2$  or  $CH_2$ ;

A<sub>2</sub> is a single, a double or a triple bond;

 $R_f$  is  $C_1$ - $C_4$  alkyl, hydroxyalkyl, or haloalkyl;

R<sub>4</sub> is C<sub>1</sub>-C<sub>4</sub> alkyl, hydroxyalkyl or haloalkyl; and

the configuration at C<sub>20</sub> is R or S.

28. (Previously presented) The method according to claim 27, wherein said vitamin D compound is 1,25-dihydroxy-21-(3-hydroxy-3-methylbutyl)-19-nor-cholecalciferol:

Docket No.: 62138US(49949)

- 29. (Previously presented) The method according to claim 2, wherein said Vitamin D<sub>3</sub> compound is a compound of the formula:
- 1-alpha-fluoro-25-hydroxy-16,23E-diene-26,27-bishomo-20-epi-cholecalciferol;
- 1,25-Dihydroxy-21-(2R,3-dihydroxy-3-methyl-butyl)-20R-cholecalciferol;
- 1,3-Di-O-acetyl-1,25-dihydroxy-16-ene-cholecalciferol;
- 1,3-Di-O-acetyl-1,25-dihydroxy-20-cyclopropyl-cholecalciferol;
- 1,3-Di-O-acetyl-1,25-dihydroxy-23-yne-cholecalciferol;
- 1,3-Di-O-acetyl-1,25-dihydroxy-16-ene-23-yne-cholecalciferol;
- $1,\!25\text{-}Dihydroxy-16,\!23Z\text{-}diene-20\text{-}cyclopropyl-26,\!27\text{-}hexafluoro\text{-}cholecal ciferol;}$
- 1,3-Di-O-acetyl-1,25-dihydroxy-16,23Z-diene-26,27-hexafluoro-19-norcholecalciferol;
- 1,25-Dihydroxy-16,23E-diene-20-cyclopropyl-26,27-hexafluoro-cholecalciferol;
- 1,3,25-Tri-O-acetyl-1,25-dihydroxy-20-cyclopropyl-23-yne-26,27-hexafluoro-19-nor-cholecalciferol;
- 1,3-Di-O-acetyl -1,25-dihydroxy-20-cyclopropyl-23-yne-26,27-hexafluoro-19-nor-cholecalciferol;

Dated September 10, 2008

1,25-dihydroxy-21(3-hydroxy-3-trifluoromethyl-4-trifluoro-butynyl)-26,27-hexadeutero-19-nor-20S-cholecalciferol;

- 1,3-Di-O-acetyl-1,25-dihydroxy-16,23E-diene-cholecalciferol;
- 1,25-dihydroxy-16-ene-20-cyclopropyl-cholecalciferol;
- 1,3-Di-O-acetyl-1,25-dihydroxy-20-cyclopropyl-23-yne-cholecalciferol;
- 1,3-Di-O-acetyl-1,25-dihydroxy-16-ene-24-keto-19-nor-cholecalciferol;
- 1,3-Di-O-acetyl-1,25-dihydroxy-20-cyclopropyl-23Z-ene-26,27-hexafluoro-l9-nor-cholecalciferol;
- 1,3-Di-O-acetyl-1,25-dihydroxy-l6-ene-23-yne-26,27-hexafluoro-cholecalciferol;
- 1,25-Dihydroxy-16-ene-20-cyclopropyl-23-yne-26,27-hexafluoro-cholecalciferol;
- 1,3-Di-O-acetyl-1,25-dihydroxy-l6-ene-l9-nor-cholecalciferol;
- 1,25-dihydroxy-21-(3-hydroxy-3-methylbutyl)-19-nor-cholecalciferol;
- 1,25-dihydroxy-21-(3-hydroxy-3-methylbutyl)-19-nor-cholecalciferol;
- 1,3-Di-O-acetyl-1,25-dihydroxy-16-ene-23-yne-19-nor-cholecalciferol; or
- 1, 3-Di-O-acetyl-1,25-dihydroxy-20-cyclopropyl-23E-ene-26,27-hexafluoro-19-nor-cholecalciferol.
- 30. (Previously presented) The method according to claim 2, wherein said Vitamin  $D_3$  compound is a compound of the formula:
- 1-alpha-fluoro-25-hydroxy-16,23E-diene-26,27-bishomo-20-epi-cholecalciferol;
- 1,3-Di-O-acetyl-1,25-dihydroxy-16-ene-cholecalciferol;
- 1,3-Di-O-acetyl-1,25-dihydroxy-16-ene-23-yne-cholecalciferol;
- 1,25-Dihydroxy-16,23E-diene-20-cyclopropyl-26,27-hexafluoro-cholecalciferol;
- 1,3-Di-O-acetyl -1,25-dihydroxy-20-cyclopropyl-23-yne-26,27-hexafluoro-19-nor-cholecalciferol;

Dated September 10, 2008

1,3-Di-O-acetyl-1,25-dihydroxy-16,23E-diene-cholecalciferol;

- 1,3-Di-O-acetyl-1,25-dihydroxy-16-ene-23-yne-26,27-hexafluoro-cholecalciferol;
- 1,3-Di-O-acetyl-1,25-dihydroxy-16-ene-l9-nor-cholecalciferol; or
- 1, 3-Di-O-acetyl-1,25-dihydroxy-20-cyclopropyl-23E-ene-26,27-hexafluoro-19-nor-cholecalciferol.
- 31. (Previously presented) The method according to claim 2, wherein said Vitamin  $D_3$  compound is calcitriol.